FOSTERING AGRICULTURAL MARKETS ACTIVITY (FARMA)

ANALYSIS

EU Market Access Constraints for Agricultural and Food Products from Bosnia and Herzegovina

February 2010

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Contract No.168-C-00-09-00102-00
FARMA - Bosnia and Herzegovina (BiH)

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Table of Contents

Abbreviations

BD	Brčko District
BiH	Bosnia and Herzegovina
BRC	British Retail Consortium
CEN	European Committee for Standardization
CENELEC	European Committee for Technical Standardization
CITES	Convention on International Trade in Endangered Species of Wild Flora and Fauna
EA	European Cooperation for Accreditation
EMS	Environmental Management System
EPPO	European and Mediterranean Plant Protection Organization
EU	European Union
FAO	Food and Agriculture Organization (UN)
FARMA	Fostering Agricultural Markets Activity
FBiH MAWMF	Federal Ministry of Agriculture, Water Management and Forestry
FBiH	Federation of Bosnia and Herzegovina
FLO	FairTrade labeling Organization
FSC	Forest Stewardship Council
FVO	Food and Veterinary Office (EU)
GAP	Good Agricultural Practices
GDP	Good Distribution Practice
GHP	Good Hygiene Practice
GlobalGAP	Good Agricultural Practices standard adopted by Euro-retailers
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Points
IAF	International Accreditation Forum
ICM	Integrated Crop Management
IFOAM	International Federation of Organic Agriculture Movement
IFS	International Food Standard
ILAC	International Laboratory Accreditation Cooperation
IMO	Institute of Market Ecology
IOAS	International Organic Accreditation Service
IPC	Integrated Pest Control
IPPC	International Plant Protection Convention
ISEAL	International Social and Environmental Accreditation and Labeling Alliance
ISO	International Organization for Standardization
ISPM	International Standard for Phytosanitary Measures
ISSC-MAP	International Standard for Sustainable Collection of Medicinal and Aromatic Plants
IUCN	International Union for the Conservation of Nature
MAC	Marine Aquarium Council
MAP	Medicinal and Aromatic Plants
MLA	Multilateral Agreements
MoFTER BiH	Ministry of Foreign Trade and Economic Relations
MPSG	Medicinal Plant Specialist Group
MRL	Maximum Residue Limits
MSC	Marine Stewardship Council
OECD	Organization for Economic Cooperation and Development
OGS	Organic Guarantee System
OIE	Office Internationale des Epizooties
PO	Producer Organization (producers, processors)
QMS	Quality Management System
RA	Rainforest Alliance
RS MAFWM	RS Ministry of Agriculture, Forestry and Water Management
RS	Republic of Srpska
SAI	Social Accountability International
Sida	Swedish International Development Cooperation Agency
SIPPO	Swiss Import Promotion Agency
SME	Small to Medium Enterprises
SPS	Sanitary and Phytosanitary Measures
SSC	Species Survival Commission
TBT	Technical Barriers to Trade
TRIPS	Agreement on Trade-related Aspects of Intellectual Property Rights
UK	United Kingdom

UN/ECE	United Nations Economic Commission for Europe
USAID	United States Agency for International Development
WHO	World Health Organization (UN)
WTO	World Trade Organization
WWF	World Wide fund for Nature

Glossary

Source: Margret Will, Doris Guenther (A Practitioners' Reference Book, 2007);

Good Agricultural Practices (GAP)	A multiplicity of Good Agricultural Practices (GAP) codes, standards and regulations have been developed in recent years by the food industry, governments and NGOs, aiming to codify agricultural practices at farm level for a range of commodities. Their purpose varies from fulfilment of trade and government regulatory requirements (in particular with regard to food safety and quality), to more specific requirements of specialty or niche markets. The objective of these GAP codes, standards and regulations include, to a varying degree: • ensuring safety and quality of produce in the food chain; • capturing new market advantages by modifying supply chain governance; • improving natural resources use, workers health and working conditions; and/or • creating new market opportunities for farmers and exporters in developing countries. • Good Agricultural Practices are "practices that address environmental, economic and social sustainability for on-farm processes, and result in safe and quality food and non-food agricultural products" (FAO COAG 2003 GAP paper).
Good Distribution Practices (GDP)	GDP guidelines aim at adjusting handling, transport and distribution procedures to the requirements of food safety. For example - European Code of Good Trading Practice (GTP) - the main principles of the European GTP code are its voluntary nature, verification and certification by independent third parties and quality management in accordance with the HACCP principles.
Good Hygiene Practices (GHP)	Guidelines for GHP aim at establishing processing, handling, transport and distribution procedures that are apt to prevent perishing due to micro-organisms, growth of pathogens on foodstuff, contamination with chemical residues or contaminants (e. g. mycotoxins). Basic rules are set out in the 'Codex General Principles of Food Hygiene'. They include requirements for the design of facilities, control of operations (including temperature, raw materials, water supply, documentation, and recall procedures), maintenance and sanitation, personal hygiene and training of personnel. Hygienic practices form an integral part of all food safety management systems, as for example within the HACCP system.
Good Laboratory Practices (GLP)	For sovereign duties (e.g. analysis, registration of pesticides), the OECD principles for GLP form the basis for quality management in laboratory control. GLP in themselves are voluntary, but have in some cases been adopted into national law and thus become mandatory in the respective countries. Otherwise, laboratories apply quality management systems according to ISO 17025.
Good Manufacturing Practices (GMP)	There are many reactions occurring during processing and manufacturing of raw materials that cause changes in composition, nutritional value, physical structure and sensory properties. The objectives of GMP are to control these changes so as to develop the desired qualities in the product, to ensure food safety and to stop or slow down any deterioration in the food. Good manufacturing practice means understanding, analyzing and controlling the manufacturing process.

Accreditation	Accreditation is the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific functions or tasks.
Benchmarking	Benchmarking is a tool used to measure and compare an institution's or firm's performance and work processes with those in other institutions/firms. The goal of benchmarking is to increase performance by adopting the best practices of benchmarking partners.
Brand	A brand is a mixture of attributes, tangible and intangible, symbolized by a trademark, which, if managed properly, creates value and influence. Brands offer customers a means to choose and enable recognition within cluttered markets. It is the promise and delivery of an experience. From the business perspective it is the 'security of future earnings'; from the legal perspective, it is 'a separable piece of intellectual property'.
Certification	Certification is defined in ISO/IEC 17000:2004 as third party attestation related to products, process, systems or persons. Certification is done by a third party and it includes surveillance activity. Certification is an asset and an advantage, both for the producer and for the customer, distributor and consumer (see also Figure 1).Certification is very useful in situations in mass-produced products where their characteristics cannot readily be inspected. The standard for product certification bodies is ISO/IEC Guide 65 - General requirements for bodies operating product certification systems.

Aside from product certification, another major type of certification is management system certification, especially quality and environmental management systems which have emerged in the last 20 years. Management system certification involves auditing the conformity of an organization's implementation of its policies and procedures in accordance with the requirements of quality and environmental management system standards, such as ISO 9001, ISO 14001 etc.

There are several other sector-specific management system standards that are the basis for certification, and more are emerging. |
Competent Authority	The Competent Authority in EU is the official government agency possessing jurisdiction. It is the authority, which the EU Member States designate (or accept in third countries) as responsible for performing the duties arising from food control requirements.
Conformity Assessment	The ever-increasing technical complexity of industry and business means that it is becoming increasingly important to be able to demonstrate that what is being supplied actually meets the requirements specified or claimed. Such a demonstration is called conformity assessment. Conformity assessment can be applied to a product, a process, a system, a body or persons and includes activities such as testing, inspection and certification.
Contaminants	Substances that – in contrast to the intentional use of phytosanitary products or veterinary drugs – can unintentionally enter food during production, processing or marketing. These can include aflatoxins, nitrate and heavy metals or environmental pollutants, such as dioxins.
Critical Control Point (CCP)	A step within the production/processing system at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.
Due Diligence	Care (due care) exercised by an ordinarily prudent or reasonable party or entity to avoid harm to another party or their property. Failure to make this effort is considered negligence.

Environmental standards	Environmental standards focus on the management and conservation of the natural resource base (soil, water, air, plant and animal genetic resources, etc.), in a sustainable manner as to ensure the attainment and continued satisfaction of human needs for present and future generations.
EU Regulation	The text of the law must be applied directly by all EU member states without changing requirements or criteria.
EU Directive	The text of the law must be interpreted and incorporated into national law by each member state; this allows member states flexibility to make changes to criteria such as setting national tolerances for chemical contaminants rather than using values given in the EU Directive.
EU Decision	A commission decision is a specific time limited measure for additional official controls, and is normally made in response to recognition of a risk to human, plant or animal health via an existing or emerging risk.
Equivalence	Barriers to international trade could be eliminated if members of the World Trade Organization (WTO) accept that regulations different from their national provisions fulfill the same policy objectives, albeit by different means. For example, recognition of equivalence of sanitary or phytosanitary measures does not require sameness of measures, but the acceptance of alternative measures that meet an importing member's appropriate level of sanitary or phytosanitary protection.
Food Hygiene	All measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff, taking into account its intended use.

Generic management system standards	In this context, "generic" means that the requirements formulated in the standard can be applied to any organization, regardless of the product or service it produces or offers, regardless of the size and type of organization, whether it is a business enterprise, a public administration or a government department.
Horizontal standards	Provision of rules across the food chain encompassing all aspects ranging from farm to fork, which are common to all foodstuffs (such as food hygiene, labeling, food and feed control, contaminants, etc.).
Maximum Residue Levels (MRL)	Maximum Residue Levels (MRLs) are the maximum level of named active ingredients (veterinary drugs, pesticide residues) in foods that can be legally sold for human consumption.
Mutual Recognition Agreement (MRA)	To facilitate trade, exporting and importing countries may enter into Mutual Recognition Agreements (MRA), thus formally recognizing that the inspection and certification system of one country is equivalent to that of the partner country. Recognizing that the certification system provides the same level of protection, controls in the importing country can be reduced.
Private label	Private labels are generated by retailers with a view of distinguishing their offer from the offer of other retailers. Private labels bear the name of the retailer. In Europe private labels have become a dominant issue against supplier brands: on average 45% of products are sold via private label.
Sanitary and Phytosanitary (SPS) Measures	Refers to all measures intended to protect human, animal or plant health.

Technical Barriers to Trade (TBT) measures	Refers to non-health related measures such as marking, labelling, packaging, market grade standards and conformity assessments to EU standards.
Traceability	Traceability means the ability to trace and track a food, feed, food-producing animal or substance through all stages of production and distribution (including import, from and including the primary production of food, up to and including sale or supply to the final consumer and, where relevant to food safety, the production, manufacture and distribution of feed).
Vertical standards	Provisions applicable to specified products or product groups (such as fresh fruit and vegetables, frozen fruit and vegetables, fruit juices, wine, honey, edible oil, chocolate, meat, fish, etc.).

Executive Summary

The international trade rules, EU's regulations and import procedures, private industry quality standards as well as additional performance or quality marks (that are not necessarily legally required, but become a de facto market access conditions), can be a difficult hurdle for BiH companies wishing to enter the EU, and other international, markets. In many cases, products must be tested and certified to ensure compliance with importer requirements - to prove EU requirements and private industry quality standards are being met. As a consequence, exporters from BiH not only need appropriate production, processing, handling, trading, marketing technologies and know-how but also appropriate legal and institutional frameworks, competent control and auditing.

Many previous reports[1] in BiH addressing issues in the agriculture and food sector, have identified shortcomings in the legal framework and institutional system, which are acting as major impediments for BiH producers wishing to export their products to the EU or other international markets. These shortcomings can be summarized as follows:

- Lack of transposition and implementation of EU technical regulations;

- Lack of conformity assessment procedures since BiH conformity assessment institutions are not accredited to undertake the necessary certifications;

- Lack of understanding of issues related to accreditation, standardization and certification of export of products to the EU among BiH public sector, POs and consumers;

- Lack of trained professionals and training opportunities, in specific aspects of certification and accreditation;

- High training costs for individuals and companies in meeting certification requirements.

First steps have been taken in BiH in order to harmonize agri-food legislation, to improve control, accreditation and certification schemes and to establish appropriate quality management systems and provide opportunities for BiH producers to access EU markets. However, this report highlights that exporters, legislative and control bodies, accreditation, certification, testing laboratories and advisory bodies, still need further development in order to assure food quality and safety along food supply chains, whether they target the domestic or international markets, namely:

- Agri–food legislation has to be harmonized with international standards and legislative mandates for food safety and consumer protection have to be streamlined.

- Risk-based food safety schemes have to be set up in accordance to international standards (science-based risk assessment, risk management and risk communication).

- Public and/or private inspection and certification bodies and laboratories have to be upgraded and accredited according to international standards to facilitate POs' access to competent services.

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[1] USAID Trade Assessment Report, EC Trade Related Needs Assesment Report, EC Mapiranje lanca vrijednosti, FAO Reports

- Agri and Food PO operators have to put in place, implement and maintain a procedure developed in accordance with GAP and HACCP principles and ensure traceability from farm to supermarket.

Introduction

In the context of globalization, standards and regulations have become a key issue for most food industries companies entering or competing on the international market. Comprehensive management systems such as international agreements, standards, protocols and guidelines are indicative of the serious efforts under way to ensure food quality and safety. The World Trade Organization (WTO) Technical Barriers to Trade (TBT) and Sanitary and Phyto-Sanitary Measures (SPS) agreements legalised the use of standards and technical regulations in global trade. In addition to the numerous technical regulations on food safety, plant protection and labelling developed by International bodies and national governments, the private sector has also established new standards for products and processes. The number of standards and certification programs that affect agricultural and food production has increased dramatically over the last decades.

The challenge is to build awareness about the need for proper SPS measures and to facilitate the adoption of good agricultural and manufacturing practices to meet the food safety and quality requirements. Quality must be certified so that the buyer and importing country receives, from a body they trust, the guarantees that the product they buy possesses the characteristics they are looking for. Therefore, it is essential to have a system for assessing compliance and conformity. Proving conformity with agreements, standards and technical regulations requires establishing efficient testing, certification and accreditation mechanisms that conform to the requirements of the SPS and TBT Agreements and enjoy international recognition. Thus well-equipped and internationally recognized testing and calibration facilities and certification bodies are extremely important for exporting companies wanting to benefit from trade opportunities.

Bosnia and Herzegovina is currently facing a two-fold challenge:

- Producers and processors must meet standards required by international markets;

- BiH legal and institutional framework must be aligned with the EU *acquis*, and testing laboratories, accreditation and certification bodies, must obtain international recognition.

The USAID and Sida-funded FARMA project will foster *rapid, sustainable and broad-based* economic growth through demand-driven assistance aimed at improved competitiveness of BiH agricultural and food producers. FARMA through collaborative process with BiH stakeholders will develop specific program activities where USAID and Sida assistance will yield a greatest rate of return while addressing needs of the whole (sub)sector market chain. Depending on which constraints in the market chain are determined to be priorities, FARMA will work to build capacity in meeting production quality requirements, promotion programs or processing capacity.

The purpose of the report

It is important to note that this report does not aim to provide a comprehensive review of all regulations and standards pertaining to agriculture and food nor does it aim to provide a detailed assessment of BiH's efforts in aligning its legal and institutional framework with the EU *acquis*. Such reviews have already been conducted and these have been cited in this report. Instead, this report aims to provide an overview of the main regulations and market-driven standards that are particularly relevant to FARMA's targeted subsectors: Dairy, Medicinal and Aromatic Plants, Honey, and Fruit and Vegetables.

The purpose of this report is:

- to provide brief overview of WTO rules, EU mandatory and voluntary standards that are important for international trade of agricultural and food products from BiH;

- to identify constraints that FARMA targeted sub-sectors are facing in participating in the world and EU trading system;

- to identify the necessary steps that FARMA can undertake to address constraints and expand market access for food and agriculture products with a focus on trade with the EU.

Apart from aiding FARMA project in formulating its activities in this area, the report is also expected to be useful for other stakeholders as a reference document for all standards and regulations pertaining to market access of food and agriculture products and a snapshot of the current efforts in BiH to overcome EU market access constraints.

Methodology

The report synthesizes information obtained from variety of sources:

- interviews with BiH officials;

- interviews with producers and processors in BiH;

- interviews with BiH donor organizations;

- relevant reports, laws and regulations;

Frameworks for standard settings and conformity assessment systems

Standards could be broadly classified according to the most relevant subject / category they tackle, and then according to the institutions that define and apply them. The WTO rules govern standards set by governments (or government-related institutions) while private standards are set by non-governmental entities, including civil society organizations and private enterprises and their coalitions, which may not be challenged directly before the WTO. Under the WTO TBT agreement, a standard is called a technical regulation if compliance is mandatory and a standard if it is not mandatory. With the increasing globalization of markets, international standards (as opposed to regional or national standards) have become critical to the trading process, ensuring a level playing field for exports, and ensuring imports meet internationally recognized levels of performance and safety.

In general, standards can be sub-divided into three categories: product, process and management systems. They are often used to create a framework within which an organization consistently achieves the requirements set out in product and process standards.

Table 1 Three categories of standards

Standard	Reference
Products	Refers to the quality and safety of goods or services.
Process	Refers to the conditions under which products and services are to be produced, packaged or refined.
Management System	Help organizations to manage their operations.

Internationally traded goods and services are increasingly subject to privately developed standards and to certification schemes focusing on issues as diverse as technical product specifications (many of ISO standards defining technical requirements for as many products), social standards (Social Accountability International), environmental and natural resources management standards (e.g. Forest Stewardship Council, Marine Stewardship Council) and health and consumer safety standards (e.g. GLOBALGAP and other food quality labels).

One example of differentiation of the private standards is differentiation between pre and post-farm gate standards, between business-to-business standards (B2B), business-to-consumers standards (B2C) - tied to a particular labelling or logo scheme intended for consumers) etc. In regard to the scope covered by the standards they can be categorized as vertical and horizontal standards as in table 2.

Table 2 Vertical and horizontal standards

Standard category	Cover	Example of standards
Vertical	For several or all stages of the food chain (farm to fork)	GAP, GMP, GHP, GDP, HACCP, ISO 9000, ISO 14000, ISO 22000…
Horizontal	For one stage of the food chain	Primary production at farm level GlobalGAP, BRC Packaging or similar

There is a large variation between private standards regarding the degree of inter-relationship between them and regulations. In addition, private standards may also build on the public standards infrastructure through use of certification bodies and public laboratories.

International agreements with implications for food production

The WTO rules govern standards set by governments and they are expected to be set within the framework of WTO agreements. The following agreements, which are designed to minimize discriminatory and adverse effects of international and national regulations, are of special interest with regard to agri-food standards:

- Agreement on Technical Barriers to Trade (WTO TBT);

- Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS);

- Agreement on Trade-related Aspects of Intellectual Property Rights (WTO TRIPS).

TBT Agreement

The purpose of the TBT Agreement is to ensure that technical requirements applied to a product –including packaging and labeling – and to procedures used to check conformity do not create any unnecessary obstacles to international trade. The agreement sets out a code of good practice for the preparation, adoption and application of standards by central government bodies and includes provisions describing how local government and non-governmental bodies should apply their own regulations i.e. they should use the same principles as apply to central governments.

The TBT Articles on Conformity Assessment apply to regulations and standards as well as to conformity assessment procedures - the process of testing compliance with a standard or technical regulation. Where possible, members should recognize technical requirements as equivalent (principle of equivalence) and/or procedures relating to conformity testing as being of equal value on a reciprocal basis.

Depending on the circumstances, conformity assessment can be undertaken through a process of independent verification (third-party or also commonly referred to as „certification"), buyer review (second party) or self-declaration (first party). Accreditation authorities accredit conformity assessment bodies. Accreditation authorities are usually government-owned or government-endorsed, and operate away from any political and commercial influence. Each is peer-reviewed regularly, based on evaluations against an international standard, by other accreditation authorities from around the world. Issues related to conformity assessment are managed by the ISO Committee on conformity assessment (CASCO) in cooperation with the International Electrotechnical Commission (IEC).

Most WTO member signatories have developed similar conformity assessment structures to meet their domestic needs and to facilitate international trade. Mutual Recognition Agreements (MRAs) have been established between accreditation authorities enabling certificates of compliance to be accepted by member accreditation authorities throughout the world. The International Accreditation Forum (IAF) brings together a range of institutions with the objective of ensuring global recognition for product certification and the certification of management systems. The IAF counterpart for laboratories is the International Laboratory Accreditation Cooperation (ILAC). The IAF and ILAC cooperate in matters of mutual interest with aim to ensure the application of international standards so that national certificates will be accepted throughout the world.

The EA, or European Cooperation for Accreditation, deals with conformity tests in all fields of quality management. It has a key role to play in the elimination of technical barriers to trade. This is achieved by the conclusion of Multilateral Agreements (MLAs) on the equivalence of accreditations in the relevant countries. EA covers the accreditation of laboratories, inspection bodies and certification bodies. The ISO system has long been considered the major standard setting body for international harmonized industry standards and is recognized by the TBT as providing internationally accepted standards.

Figure 1 Conformity Assessment Accreditation Hierarchy
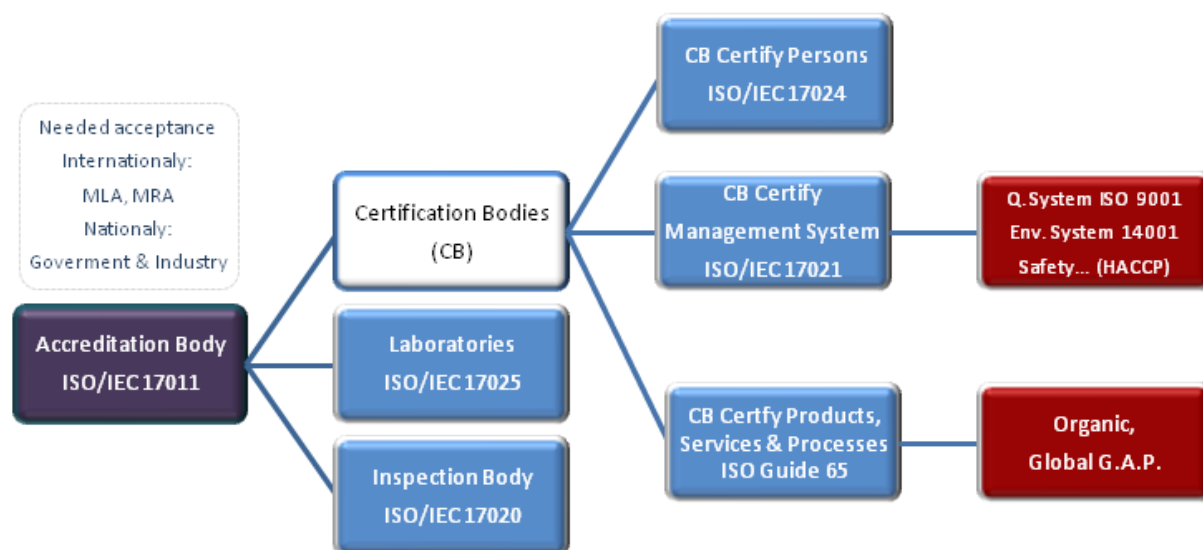
SPS agreement

The WTO SPS agreement sets out the basic rules for food safety and animal and plant health standards. It allows countries to set their own regulation but they must be based on science and measures should be applied only to the extent necessary to protect human, animal or plant health. Member countries are encouraged to use international standards where they exist. The SPS Agreement is a treaty and therefore has international legal status; it binds the States and

organizations (like the European Community) which have agreed to it. As is clear from the wording of the Agreement itself, it is first and foremost addressed to Members and, insofar as it applies to "all SPS measures". The SPS Agreement specifically defines international standards, guidelines and recommendations (so called "three sisters standards") to be:
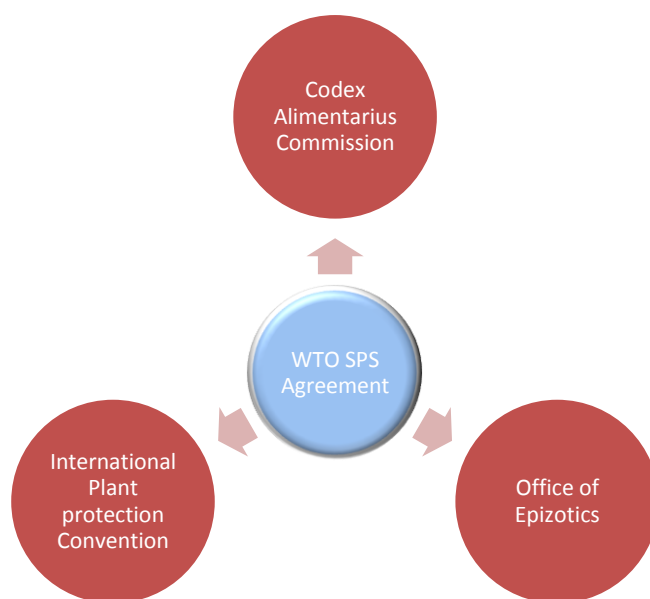
- For food safety, those established by the Codex Alimentarius Commission;

- For plant health, those developed under the auspices of the FAO's Secretariat of the International Plant Protection Convention;

- For animal health and zoonoses, those of the International Office of Epizootics;

- For matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members.

Codex Alimentarius Commission (CAC)

The Codex Alimentarius Commission is the international food standards setting body of the United Nations, a joint venture of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The fundamental mandate of the CAC is to develop international standards for consumer health protection and fair practices in food trade.

The Codex includes provisions with respect to food hygiene, food additives, pesticide residues, contaminants, labeling and presentation, methods of inspection, analysis and sampling. It also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures. The standards of the Codex Commission are not legally binding, and national adoption of Codex standards is thus voluntary. An increasing number of countries are aligning their national food standards, or parts of them (especially those relating to food safety), with those of the Codex Alimentarius. Codex Standards serve as benchmark for national regulations and in international food law disputes submitted to the WTO. The Codex contains more than 200 standards for individual foods or groups of foods.

Maximum residue limits for pesticides and veterinary drugs and maximum limits for food additives and contaminants have been established to ensure that consumers are not exposed to unsafe levels of hazardous materials. The Codex Maximum Residue Limits are recommended on the basis of appropriate residue data obtained mainly from supervised trials. The residue data thus obtained reflect registered or approved usage of the pesticide in accordance with "good agricultural practices". The Codex Extraneous Maximum Residue Limit, refers to residues of compounds, which were used as pesticides but are not any more registered as pesticides, arising from environmental contamination (including former agricultural use of pesticides) or uses of these compounds other than agricultural uses. These residues are treated as contaminants.

International Plant Protection Convention (IPPC)

The purpose of the international treaty IPPC is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control. The IPPC covers both direct and indirect damage by pests, including weeds. The provisions extend to cover conveyances, containers, storage places, soil and other objects or material capable of harboring plant pests. The IPPC is governed by the Commission on Phytosanitary Measures (CPM) which adopts International Standards for Phytosanitary Measures (ISPMs). The IPPC Secretariat coordinates the activities of the Convention and is hosted by FAO.

IPPC sets standards that are recognized by WTO-SPS and applies mainly to quarantine pests involved with international trade. The Commission governs the implementation of the IPPC. It is recently composed of representatives from the National Plant Protection Organizations (NPPO) from both contracting parties to the IPPC and FAO members.

European and Mediterranean Plant Protection Organization (EPPO)

EPPO is an intergovernmental organization of more than 40 member countries responsible for cooperation in plant protection in the European and Mediterranean region. Under the International Plant Protection Convention (IPPC), EPPO is the regional plant protection organization for Europe. EPPO makes recommendations (in the form of Regional Standards) to the National Plant

Protection Organizations of its member countries. These recommendations are Regional Standards in the sense of the revised IPPC. EPPO Standards have been developed for plant protection products and for phytosanitary measures.

Office Internationale des Epizooties (OIE)

The purpose of the OIE (Organisation Mondiale de la Santé Animale/World Organisation for Animal Health) is:

- securing transparency in animal health worldwide;

- collecting, analyzing and disseminating veterinary information;

- defining minimum health standards for international trade within its WTO mandate;

- contributing expertise to respond to the occurrence of diseases;

- encouraging coordination.

Types of standards include:

- health standards for animal and animal products trade;

- biological standards.

United Nations Economic Commission for Europe (UN/ECE)

UN/ECE aims at fostering sustainable trade relations between its member countries by providing a forum for communication among members, addressing trade, transport and environment issues and supplying statistics, economic and environmental analyses. UN/ECE commercial quality standards are used as a common trading language for buyers and sellers and as a reference for quality control. Although UN/ECE standards are voluntary multilateral standards they are of special interest in international trade since they define a common trading language, fill the gap between food safety regulations and marketing and define commercial quality for foodstuffs.

European Committee for Standardization (CEN) and European Committee for Electrotechnical Standardization (CENELEC)

CEN and CENELEC have been officially recognised as the European Standards Organisation in their fields by the European Commission through Directive 83/189/EEC. The legal bases for the activities of CEN in food-related issues are laid down e. g. in the 'Council Directive 89/392/EEC on the approximation of the laws of the Member States relating to machinery' (basic requirements for safety and health for specific machine types such as food processing machines).

Organization for Economic Cooperation and Development (OECD)

The OECD elaborates common criteria (procedures, rules, standards) with the objective of facilitating international trade. The OECD produces internationally agreed instruments, decisions and recommendations to facilitate the adaptation of quality standards to present production, trade and marketing conditions, the promotion of uniform quality control procedures and the dissemination of quality assurance guidelines.

The OECD supplies reference for the certification and standardization of certain agricultural commodities (fruit and vegetables) and inputs (seeds). Depending on countries, various schemes exist ranging from direct enforcement to accreditation procedures. The OECD Scheme for the

Application of International Standards for Fruit and Vegetables facilitates the adaptation of quality standards (production, trade and marketing) by promoting uniform quality control procedures and dissemination of quality assurance guidelines. The OECD scheme for varietal certification of seed moving in international trade ensures the varietal identity and purity of seed.

OECD also provides assistance to member governments to co-operate in assessing and reducing the risks of agricultural pesticides and to improve the efficiency and effectiveness of pesticide regulations in OECD countries.

International Standard Organization (ISO)

ISO is a network of national standards bodies of more than 150 countries. ISO member institutes are either part of the governmental or private sectors (e. g. Industry associations) in their respective countries. In such a way, ISO is able to facilitate consensus agreements on solutions that meet the requirements of the business community as well as those of other stakeholders, such as consumers or the society in general.

As the leading developer of international standards, ISO cooperates in a participatory way with public and private stakeholders worldwide to lay down requirements for products, services and processes, for conformity assessment as well as for managerial and organizational practices. ISO itself does not certify companies nor does it accredit certification bodies. For this reason, the ISO logo can not be used in connection with certificates or on product labels.

Certification against ISO standards is carried out by either governmental or private certification bodies. Even though ISO standards are voluntary, certain ISO standards such as health, safety and /or environmental standards – have been adopted in some countries as part of the national regulatory framework, or are referred to in legislation. ISO standards are voluntary, although they may become a market access requirement as they have become an integral part of an increasing number of standards at all levels. ISO standards cover the following fields: terminology, laboratories, accreditations, inspections, certification of personnel, certification of products, certification of management systems, environmental management systems, multilateral agreements (MLAs) and suppliers of conformity declarations.

ISO 9001:2008	ISO 9001: 2008 (updated from the original ISO 9001: 2000) is the best known of the ISO 9000 family of International Standards for quality management. The standard gives the requirements for a quality management system. ISO 9001: 2008 does not give requirements for specific products or services; rather, it provides a set of generic requirements relating to the processes of development and production, and how they will be managed, reviewed and improved in order achieve customer satisfaction. The requirements call for the processes to be comprehensively documented as procedures to which staff are expected to consistently conform. This is with the aim of meeting the needs and expectations of the customer and helping organizations to comply with applicable regulations. Implementation involves making production procedures explicit (say what you do), documenting them, ensuring they are followed and checking they are effective. A quality management system can be audited by an independent certification body as conforming to the standard (leading to an ISO 9001: 2008 certificate), although this is not compulsory unless it is a market or regulatory requirement.
	Assessments for certification are carried out against the ISO 9001: 2008 standard, which is the only certification standard in the ISO 9000 family. To comply with ISO 9001: 2008 an organization needs to review its processes in accordance with the standard's requirements in order to meet the needs and expectations of the "customer base". The ISO

requirements cover a wide range of topics:

- Management commitment to quality.

- "Customer' focus".

- Adequacy of an organization's resources.

- Employee competence.

- Process management (for production, service delivery and relevant administrative and support processes).

- Quality planning.

- Design, purchasing, monitoring and measurement of its processes and products.

- Processes to resolve customer complaints.

- Corrective/preventive actions.

- A requirement to drive continual improvement of the organization.

- A requirement to monitor 'customer' perceptions about the quality of the goods and services it provides.

The vast majority of ISO standards are highly specific to a particular product, material, or process. However, ISO 9001 (quality) and ISO 14001 (environment) are, generic management system standards", which means that the same standard can be applied to any organization, large or small, whatever its product or service, in any sector of activity, and whether it is a business enterprise, a public administration, or a government department.

ISO 22000:2005	ISO 22000:2005 is a standard designed to ensure safe food supply chains and the first of a family on food safety management systems. ISO 22000 applies to all organizations, regardless of their size, that impact the food chain. This includes ingredient suppliers, equipment manufacturers, package suppliers, service providers, farmers, food processors, catering and retailing organizations. ISO 22000 combines the ISO 9001 process-based management system and Hazard Analysis and Critical Control Point (HACCP) principles and makes it easier for organizations worldwide to implement the Codex HACCP system for food hygiene in a harmonized manner. HACCP is a Food Safety methodology that relies on the identification of Critical Control Points (CCPs) in food production and preparation processes. Closely monitored CCPs will ensure that food is safe for human consumption. It avoids traditional "end product testing" and seeks to identify hazards and reduce risks throughout all HACCP[2] Principles.
	ISO 22000:2005 Food Safety Management System Standard Series:
	ISO 22000:2005, Food safety management systems - Requirements for any organization in the food chain give the basic requirements for a food safety management system to ensure food safety along the food chain, up to the point of final consumption.
	ISO/TS 22004:2005, Food safety management systems - Guidance on the application of ISO 22000:2005 gives guidance on the use of ISO 22000, which is based on the principles of the HACCP system developed by the Codex Alimentarius Commission and is designed to be

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[2] Growing demand for harmonized food standards in international trade fueled the Codex Alimentarious Commission to adopt HACCP as the international standard for food safety. Today HACCP is being adopted worldwide, on the recommendation of the UN's Codex Committee and is promoted and incorporated into Food Safety Legislation in many Countries.

applied together with relevant standards published by that organization.

ISO 22005:2007, Traceability in the feed and food chain - General principles and basic requirements for system design and implementation gives the principles and specifies the basic requirements for the design and implementation of a feed and food traceability system.

ISO/TS 22003:2007, Food safety management systems - Requirements for bodies providing audit and certification of food safety management systems and ISO/IEC 17021:2006, Conformity assessment - Requirements for bodies providing audit and certification of management systems, have been developed for certification bodies and the accreditation bodies that approve them as competent. Certification of a food safety management system to ISO 22000 is not a requirement of the standard, but is one means of providing assurance that an organization has implemented a system for the management of food safety in line with its policy.

ISO 14001: 2004	ISO 14001 has been written to support implementation of Environmental Management Systems (EMS) in many different types of organizations. Requirements for certification are the development of an environmental policy, including an implementation and communication plan, definition of responsibilities, staff training activities, documentation and monitoring. A growing number of farms are being certified against the ISO 14001 standard. More and more ISO 14001 certified firm claims can also be found on products. ISO 14001 is rapidly becoming a default certification for plantations.

ISO 14001:2004 is the certification standard similar to ISO 9001:2000 in concept and structure as both standards concern processes and not products directly. Both will share some similar benefits and limitations due to these similarities. ISO 14001:2004 (the latest version) is primarily concerned with 'environmental management' or what the organization does to minimize harmful effects on the environment caused by its activities. The ISO 14000 family consists of standards relating to Environmental Management Systems (EMS), which are tools to help the organization develop its environmental policy, objectives and targets, and classify them by when they apply to:

The organizational level (implementing EMS, conducting environmental auditing and related investigations, and evaluating environmental performance).

Products and services (using environmental declarations and claims, conducting life cycle assessment), addressing environmental aspects in product standards, and understanding terms and definitions).

ISO 14001:2004 ensures that organizations are aware of environmental aspects of their work in order to minimize negative impacts and improve environmental performance. ISO suggests that the standard can provide significant tangible benefits, including:

Reduced raw material/resource use.

Reduced energy consumption.

Improved process efficiency.

Reduced waste generation and disposal costs.

Utilization of recoverable resources.

The standard can be implemented by a wide variety of organizations, whatever their current level of environmental maturity. However, a commitment to compliance with applicable environmental legislation and regulations is required, along with a commitment

to continuous improvement.	
ISO/IEC 17025	ISO/IEC 17025 is the main standard used by testing and calibration laboratories. There are many commonalities with the ISO 9000 standard, but ISO/IEA 17025 adds in the concept of competence to the equation. There are two main sections in ISO/IEC 17025: Management requirements – primarily related to the operation and effectiveness of the quality management system within the laboratory. Technical requirements - address the competence of staff, methodology and test/calibration equipment. Laboratories use ISO/IEA 17025 to implement a quality management system aimed at improving their ability to consistently produce valid results. A documented quality management system is a prerequisite for accreditation from an Accreditation Body. Since the standard is about competence, accreditation is simply a formal recognition of a demonstration of that competence.

International Food Safety Standard

In 2002 German retailers developed a common standard for food safety management systems, called International Food Standard (IFS). French food retailers (and wholesalers) joined the IFS Working Group in 2003 and contributed to develop the current 4th version of the standard. The standard has been designed as a uniform tool to ensure food safety and to monitor the quality level of producers of retailer branded food products. The standard can apply for all steps of the processing of foods subsequent to their agricultural production.

The aim of the IFS is to create a consistent evaluation system for all companies supplying retailer branded food products with uniform formulations, uniform audit procedures and mutual acceptance of audits, which will create a high level of transparency throughout the supply chain. The IFS defines requirements in content, procedure and evaluation of audits and a requirement profile for the certification bodies and auditors.

The audit against the IFS standards is based on the following criteria:

- Foundation level - these criteria are considered as minimum requirements for the international food industry.

- Higher level - these criteria are considered as a high standard in the food industry.

- International Social and Environmental Accreditation and Labeling Alliance (ISEAL Alliance)

Standards and accreditation programs of ISEAL members are international in nature and focus on production and trade methods and processes. These characteristics combine to make ISEAL member organizations unusual within the fields of conformity assessment and voluntary labeling instruments. As such, members have prioritized the need to monitor and provide input into policy development. In this way, members can ensure that interpretations of regulatory issues and voluntary frameworks are favorable to member programs, and that these types of conformity assessment programs are recognized as legitimate. Taken individually, the standards and verification systems of ISEAL members represent efforts to define issue-specific elements of social and environmental sustainability.

The ISEAL Code of Good Practice aims at improving the quality of standard-setting processes by establishing objective criteria for standard setting, capacity- building of members as well as by obliging members to continuous improvement of their programmes and to participate in internal peer reviews against ISO/IEC Guide 17011.

Full members (organizations meeting requirements for good practice in either their international standard-setting or international accreditation practices include:

- FLO, Fair-trade Labeling Organizations

- FSC, Forest Stewardship Council

- IFOAM, International Federation of Organic Agriculture Movements

- MAC, Marine Aquarium Council

- MSC, Marine Stewardship Council

- RA, Rainforest Alliance

- SAI, Social Accountability International.

Fairtrade Labeling Organizations International (FLO)

The Fair-trade Labeling Organizations International (FLO) is part of a worldwide network of Fair Trade organizations supporting producers, awareness raising and campaigning for changes in the rules and practices of conventional international trade. FLO unites 20 labeling initiatives that promote and market the Fairtrade label in their countries. As the leading Fairtrade standard setting and certification body, FLO intends to enable sustainable development and empowerment of disadvantaged producers and workers in developing countries. General principles are: social, economic and environmental development.

Product Specific Standards for small farmers' organizations and traders of their products have been elaborated for: bananas, cacao, coffee, dried fruit, fresh fruit (except bananas) and fresh vegetables, herbs and spices, fruit juices, honey, nuts and oil seeds, quinoa, rice, cane sugar, tea, wine grapes and seed cotton

International Federation of Organic Agriculture Movements (IFOAM)

The IFOAM was established as an umbrella organization for national organic agriculture associations. Members also include certification bodies, traders and processors, research and training institutions, consultancy agencies and others working in the organic sector. IFOAM's work is based on its four principles of organic agriculture:

- the principle of health,

- the principle of ecology,

- the principle of fairness, and

- the principle of care.

IFOAM works towards the worldwide adoption of ecologically, socially and economically sound systems that are based on these principles and represents the organic agriculture movement at the United Nations and other inter-governmental agencies. IFOAM is a grassroots and member-

driven organization, which has the IFOAM General Assembly as its base. An important part of IFOAM is its Organic Guarantee System (OGS), which is designed to facilitate the development of organic standards and third-party certification worldwide, and to provide an international guarantee of these standards and organic certification. The IFOAM Basic Standards and the Accreditation Criteria are two of the main components of the OGS.

The IFOAM Basic Standards (IBS) provide a framework for standard-setting and certification bodies to develop their own certification standards based on specific local conditions. While continuously adopting newly developed organic practices worldwide, the IBS reflect the current state of organic production and processing methods. The IFOAM Accreditation Criteria (IAC) establishes the requirements for conducting organic certification. The IAC are based on the ISO 65:1996 for the operation of certifying bodies and are developed to reflect the particular circumstances of certifying organic production and processing.

GlobalGAP

GlobalGAP (previously EurepGAP) is now one of the leading private standards initiatives in Europe in which several major retailers and food processing companies are involved. GlobalGAP membership is open to all relevant food retailers, producers and suppliers which agree to the terms of reference of the organization. Membership is divided into three groups:

- Retailers;

- Producers/suppliers;

- Associates (i.e. members engaged in activities related to the food industry or exercising standardization-related activities).

GlobalGAP is an auditable standard promoting Good Agricultural Practices (GAP). It includes topics such as Integrated Crop Management (ICM), Integrated Pest Control (IPC), Quality Management System (QMS), Hazard Analysis and Critical Control Points (HACCP), worker health, safety, welfare and environmental pollution and conservation management. GlobalGAP consists of 1 Integrated Farm Assurance standard which integrates three main product groups: (1) Crops, (2) Livestock and (3) Aquaculture. These product groups are divided again into more specific products such as fruit & vegetables, tea, pigs, salmon etc. For all products and product groups GlobalGAP developed requirements that aim for: safe products, traceability through the supply chain and environmental aspects of agriculture. When putting requirements for one product group together, in practice one can certify that product group with one single audit. So, a farm with different products can be certified for all these products with one audit.

GlobalGAP does not issue the certificates itself but has authorized registered certification bodies to do this. To get the GlobalGAP certification, the producer, or group of producers, needs a complete administrative system to keep track of all farm activities. This requires a sufficient administrative and financial capacity, and consequently it is easier for large-scale producers to meet the requirements. The GlobalGAP-certified producer may also have an advantage when selling products to retailers that require GlobalGAP certification. There is no special price premium or product label associated with GlobalGAP, as it is a minimum standard focused on business-to-business relations.

British Retailer Consortium

The BRC Global Standard grew out of the initiative of British private label retailers. The British Retail Consortium is the leading trading organization in the UK. The BRC Global Standard guaranteeing minimum standards. It includes quality management system audits in food processing companies.

BRC Global Standard - Food

The standard covers topics such as: the HACCP system; quality management; factory environment standards; and product and process control. The standard is meant for use by food service companies, catering companies and food manufacturers. It covers the supply of retailer-branded products, branded food products and processed or prepared food or ingredients. The standard is intended to be implemented by suppliers of retailers recognizing the standard (i.e. BRC members).

BRC Global Standard - Packaging

Manufacturers have an obligation to put appropriate systems and controls in place to ensure the suitability of their packaging for safe food use. This Standard is most applicable to manufacturers of food contact packaging. The standard covers the following topics: organization; hazard and risk management system; technical management system; factory standards; contamination control; personnel; risk category determination; and the evaluation protocol.

ISSC- MAP & FairWild Standards

The development of an International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants (ISSC-MAP) is a joint initiative of the German Federal Agency for Nature Conservation (BfN), World Wide Fund for Nature (WWF)/TRAFFIC, Germany, the World Conservation Union (IUCN), Canada, and the IUCN Medicinal Plant Specialist Group (MPSG) of the Species Survival Commission (SSC). Based on existing general conservation guidelines, the initiative and the final standard is intended to provide specific guidance and criteria for the sustainable wild collection of MAPs.

The agreement to join ISSC-MAP with FairWild Foundation was formalized in 2008. The application and further evolution of the combined FairWild Standard will be overseen by the FairWild Foundation, with IUCN, WWF and TRAFFIC each having initial representation on the Foundation's governing and technical bodies, alongside representatives from the organizations involved in FairWild Foundation's founding: SIPPO (Swiss Import Promotion Programme), Forum Essenzia e.V and IMO (Institute for Market Ecology).

The Foundation provides a certification system and standard for socially and ecologically positive collection and production of indigenous plants. Several enterprises are on the way to meet these criteria, e.g. in Europe, Asia, and South America, with FairWild certified herbal products expected to begin to appear in the European and North American markets in 2010.

Harmonization of EU regulatory requirements under WTO Agreements and minimal requirements for global trade

The EU is a signatory to WTO's SPS and TBT agreements and most EU regulatory requirements comply with the SPS and TBT agreements. However, some EU measures require higher standards than those set under the WTO agreements. The food control system in the EU is based on:

- Forming one agency to focus on food safety;

- Using risk analysis to design regulation;

- Recognizing that a farm-to-table approach is often desirable for addressing food safety hazards;

- Adopting the HACCP system as a basis for new regulation of microbial pathogens in food;

- Adopting more stringent standards for many food safety hazards;

- Adding new and more extensive regulation to handle newly identified hazards;

- Improving market performance in food safety through provision of information.

The main framework of the new harmonized framework for food and feed hygiene consists of the following regulations and directives:

Table 3 EU Regulations related to food safety

Main Regulations	EU Official Journal
R.178/2002 EU food law	L 31 1/2/02
R. 852/2004 Hygiene of foodstuffs	L226 25/6/04
R. 853/2004 Hygiene rules food animal origin	L226 25/6/04
R. 854/2004 Official controls on products of animal origin	L226 25/6/04
R. 882/2004 Official controls	L191 28/5/04

Apart from this, there are numerous regulations, directives and decisions dealing with specific issues food law implementation. In accordance to EU law there is a clear division of responsibility for food safety between the private food business operator and the competent authorities of government:

The food business is charged with legal responsibility for ensuring food safety, and some establishments (those handling products of animal origin) need to approved and registered by competent authorities;

The competent authorities (government) have legal responsibility for establishing official control systems and verifying compliance with food law and food hygiene in particular. Application of the HACCP system to food production has become mandatory, as a result of the European directives.

The European Food Law has different import requirements for:

- Food of animal origin;

- Food of non-animal origin; and

- Food containing both, processed ingredients of animal origin and of plant origin.

Countries wishing to export food products to the EU are required to demonstrate that, for the specific products they wish to export, they have and can maintain standards at least equivalent to those applicable in the EU itself. Products exported to EU have to fulfill phytosanitary, veterinary, food safety and marketing standards.

The Food and Veterinary Office (FVO) conducts monitoring and control programs for both food products originating within the EU and products originating in countries outside the EU. For non-EU countries, the FVO has the task of ensuring imports into the EU are produced under conditions at least equivalent to those in the EU.

EU legislation represents the minimum requirement for market access. However, many of the larger retailers and some wholesalers require suppliers to demonstrate compliance with independently verifiable private standards such as the GlobalGAP or the British Retail Consortiums (BRC) Global Technical Standard as this is an effective way of ensuring that suppliers have the necessary management and control systems in place.

The EU importer is responsible for ensuring that all foodstuffs imported into the EU comply with the requirements of EU food law. As a result the EU importer is obliged to require third country suppliers to meet the requirements of EU food law.

The regulatory framework for sanitary and phytosanitary measures (SPS) is designed to protect human and plant health by ensuring that imported fruits and vegetables are not contaminated with harmful levels of pesticides or other chemical contaminants, micro-organisms capable of causing harm to human health and plant pests and diseases that could harm crops, ornamentals or wild plants in Europe. As food safety measures within the EU are based on scientific assessment of the likely risk to health of a given hazard, for this reason products of animal origin that represent the greatest risk to health are subject to strict import controls including EU approval of exporting countries national food control systems and EU approval and registration of food businesses wishing to export to the EU or involved in production and processing of food intended for export to the EU.

The majority of regulatory requirements for accessing EU markets deal with food safety and phytosanitary issues and thus come under SPS measures. However, exporters of selected commodities are required to meet quality specifications defined under the market grade standards regulation (EC/2200/1996) with proof of compliance with the standards coming in the form of a certificate of conformity (EC/1148/2001).

Market grade standards (EC/2200/1996) and certificate of conformity with market grade standards (EC/1148/2001)

Regulation EC/2200/1996 defined the need for quality standards for fresh fruits and vegetables to ensure that produce offered to the consumer is of acceptable quality, accurately labeled and that produce of unsatisfactory quality is kept off the market. Produce subject to a market standard under EC/2200/1996 can only be sold by a retailer if it conforms to the specified standards. For commodities where a standard exists, quality is divided into three classes (extra class, class 1 and class 2) with the requirements for each class being detailed in the annex to the relevant standard. From 31st March 2003 it has been mandatory to demonstrate compliance by providing a certificate of conformity (defined under EC/1148/2001) with each shipment of any of the commodities.

Hygiene rules for foods of non-animal origin (EC/852/2004)

Regulation EC/852/2004 introduces the concept of ensuring food hygiene at all stages in the food chain. The EU food importer (and therefore the third country supplier) must consider the following:

- EU food business must ensure food safety by preventing contamination of products from any source (air, soil, water, fertilizer, feed, chemicals, worker hygiene, storage, handling and disposal of wastes);

- Foodstuffs imported into the EU shall comply with the EU hygiene standards or with equivalent standards.

The specific measures for ensuring food safety and hygiene are divided into those applying to primary production (Annex IA) which in practice means the farm and those dealing with food processing (Annex II) which in practice refers to high care facilities in pack-houses for pre-cut fruit and vegetable production and facilities for production of fruit and vegetable juices. Regulation EC/852/2004 specifies requirements for most food businesses to have a HACCP system in place. However, farmers should also find aspects of the HACCP approach useful for looking a type of product, intended use, process flow, hazard analysis, control measures, monitoring, record keeping and verification that the good agricultural practice management and control system is achieving the desired outcomes in terms of food safety and hygiene.

The measures specified in Regulation EC/852/2004 represent a convergence between regulatory requirements and voluntary private sector standards such as GlobalGAP and the British Retail Consortium (BRC) Global Technical Standard. This is particularly pertinent in the sense that in the absence of detailed guidance documents or codes of practice from either the EU or national agencies of member states, food businesses will need to make use of existing private sector codes of practice and guidance materials to decide how best to meet the requirements of the law.

Safe and effective use of pesticides

In the area of pesticide residues it is necessary for third country suppliers to ensure that no pesticides banned in the EU are present on the produce, and that levels of permitted pesticides do not exceed the maximum levels permitted under EU law. The legal provisions for these requirements are covered under Directives 79/117/EEC, 91/414/EEC and Regulation EC/396/2005.

Food cannot be imported into the EU if it has been treated or contaminated with any of the compounds listed under the directive. Producers and exporters in third countries need to ensure

that banned pesticides are not present in the farm and cannot contaminate produce intended for export. There is no need for a certificate for export, but produce is subject to random testing at the point of entry, distribution or retail sale within the EU.

Harmonized MRL's for pesticides (EC/396/2005)

Maximum residue limits (MRL) are the legal limit or maximum permitted level of a chemical contaminant in food or feed. MRLs are not toxicological limits and thus a chemical detected in a food at its MRL will not represent a risk to human health. MRLs are useful as measures for verifying good agricultural practice on the farm and confirming that the produce does not represent a risk to health. In practice the grower and exporter need a method to ensure that the level of chemical will have reduced from the amount applied during spraying to below the MRL by the time the product reaches the EU.

EC Directive 2001/110/EC relating to honey

In the EU following legislation applies regarding honey:

- Vertical legislation refers to specific products e.g. Honey Directive: 2001/110/EC, 2001/158/EC, 2002/337/EC;

- Horizontal legislation refers to all food stuffs e.g. for contaminants, additives, labeling, Regulation EEC 2377/90, 1530/2002, 2004/621/EC, 853/2004;

European countries are permitted to import honey from outside the EU, only if the exporting country is on the EU's list of so-called 'third countries'. Being listed as a 'third country' means that the country has met EC animal health and public health requirements governing trade and export. For products of animal origin, a country must have in place a national residue control program. According to EU Council Directive 96/23, countries that are unable to present such a program and comply with the strict requirements set out in this Directive will not be included on the list of approved 'third countries' for trading products of animal origin. EU Directive 96/23 establishes the frequency and level of sampling and the groups of substances to be controlled for each food commodity. EU Directive 97/747 provides further rules for certain animal products.

Chemical contaminants in food (Regulation EC/466/2001)

The contaminants in food regulation establishes the maximum permitted levels of chemical contaminants (other than pesticides) such as nitrates, mycotoxins (fungal toxins), heavy metals (lead, cadmium & mercury) and 3-monochloropropane-1,2-diol (3-MCPD) in a range of foods of both animal and non-animal origin. Laboratory testing of end products for the presence of chemical contaminants is useful for verifying that food safety management measures are working but cannot be used to control the hazard in the field. (Some of a requirement for compliance with private sector standards such as GlobalGAP makes commercial sense for suppliers seeking to meet EU regulatory requirements.

Phytosanitary measures (Directive 2000/29/EC)

The plant health directive (2000/29/EC) is designed to regulate entry and spread of plant pests and diseases within the EU. The EU requires all countries wishing to export to member states that they have a competent national plant protection authority (NPPA) capable of conducting phytosanitary inspection and certification prior to export.

BOSNIA FARMA PROJECT

All exporters of products of plant origin listed in annex V of Directive 2000/29/EC must submit their shipment for inspection by officers of their NPPA and obtain a plant health (phytosanitary) certificate issued in accordance with the requirements of this Directive to certify that the products are free of the prohibited pests and diseases listed in annexes of the directive. It is imperative that exporters conduct their own quality control checks to ensure that shipments are free of pests and it also pays to work with the authorities to ensure that official inspections are conducted correctly.

Wood packaging (Directive 2004/102/EC)

The wood packaging directive was introduced so that the EU would be in compliance with the International Standard for Phytosanitary Measures (ISPM15) developed by the International Plant Protection Convention (IPPC) that provides guidelines for regulating wood packaging materials in international trade.

Organic production (EC/834/2007, EC/889/2008 and 1235/2008)

Third country suppliers wishing to export under an organic label must meet all the requirements for organic production specified in Regulation EC/834/2007. To demonstrate compliance the operator must register with an approved organic certification body and implement an organic certification scheme incorporating independent verification of compliance on an annual basis.

Eight countries have successfully demonstrated to the EU that they have equivalent national systems for control of organic production and free importation of organic products is allowed from these countries. Individual businesses in the majority of countries that have not demonstrated national equivalence of systems for organic production require prior approval for export and a certificate of importation (issued by a national or international body recognized by the EU) to accompany every shipment.

Third country suppliers of organic fruits and vegetables must also comply with all of the regulatory requirements for SPS and TBT specified for conventional production under with specific requirements being determined by whether the product is processed or comes under the market grade standards.

Geographical Indications, Protected Designation of Origin (PDO/PGI/TSG, EC/510/2006, EC/509/2006)

The introduction of PDO, PGI and TSG systems in EU started in 1992. The main objective was to differentiate food products by guaranteeing their region-of-origin or traditional production methods. Consumers are informed by product labels. The focus is on product quality. Relevant are Council Regulation (EC) No 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs and Council Regulation (EC) No 509/2006 on agricultural products and foodstuffs as traditional specialties guaranteed. Further details about PDO, PGI and TSG are described below:

- PDO (Protected Designation of Origin) covering foodstuffs which are produced, processed and prepared in a given geographical area using recognized know-how;

- PGI (Protected Geographical Indication) covering foodstuffs for which the geographical link must occur in at least one of the stages of production, processing or preparation;

- TSG (Traditional Speciality Guaranteed) does not refer to the origin but highlights traditional character, either in the composition or means of production.

BiH institutional context

Overall situation

As a potential candidate for EU accession, BiH needs to harmonize its veterinary, phytosanitary, and food safety legislation to those of the EU. BiH is still at the early stages of alignment with the EU acquis. The quality and regulatory infrastructure is still being developed to meet EU requirements. In addition, BiH is not yet a member of the WTO even though the WTO agreements (SPS and TBT) form the basis for harmonization of international regulation of food safety, quality, animal and plant health in global trade.

On the basis of the constitutional structure of BiH, the policy-making and decision-making competences for agriculture, public health, food industry, trade and tourism were given to the Entities and in the F BiH to the 10 cantons. BiH lacks a State-wide agricultural policy and strategy. Efforts have been made, with assistance from foreign donors, to create a state-level Ministry of Agriculture, however those efforts have not been bearing fruit so far. A Sector for Agriculture, Food, Forestry and Rural Development was established within the Ministry of Foreign Trade and Economic Relations (MoFTER) as there is no national level Ministry of Agriculture. MoFTER works in co-operation with the competent bodies of the Entities to negotiate, develop and ensure the effective implementation of obligations under an international, multilateral, regional and bilateral treaties, agreements and conventions committed to by the Government of BiH. The Cantons have significant role in measures implementation, including support to producers and inspection. The Municipalities have mainly an administrative function in support to the entities' MAFWM, with special emphasis on inspectorate competences (land, agriculture and veterinarian), farmer registration and entities grant schemes. Design and implementation of consistent agricultural policies is hindered by involvement of many different institutions in policy making and the lack of coordination between the entities. A wide range of institutions have an impact on the agricultural policy in BiH. Presently the institutions involved are MoFTER, State Veterinary Office, Food Safety Agency, Plant Health Protection Administration, Entity Ministries of Agriculture and Department of Agriculture - Brčko District.

Table 4 Competences of the different Ministries of Agriculture in BiH[3]

National Level	Entity Level			Cantonal Level
The Ministry of Foreign Trade and Economic Relations (MoFTER) of BiH	Ministry of Agriculture, Forestry and Water Management of Republika Srpska (RS MAFWM)	Ministry of Agriculture, Forestry and Water Management of FBiH (FBiH MAWMF)	Department of Agriculture, Forestry and Water Management of Brčko District	Cantonal Ministries of Agriculture, Water Management and Forestry and Departments for Agriculture of cantonal Ministries of Economy

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[3] Source: BDPA, Bernard Cartella, Twinning Project, "Institutional Support to the establishment of a Ministry of Agriculture and Rural Development", 2006.

Foreign trade policy and customs tariff policy of BiH. Enforcement of the single economic space. Consumer protection and competition. Co-ordination of International economic aid to BiH. Veterinary matters: general legislation, international cooperation, Inter-Entity coordination, and animal registration. Food safety legislation and enforcement	Drafting of legislation Policy making Inspection Administrative work Processing of subsidy applications Extension and Selection work	Drafting of legislation Policy making Inspection Administrative work Processing of subsidy applications	Administrative and regulatory functions related to agriculture, veterinary, forestry and water management. Development of rural areas including investment development. Inspection function is the responsibility of the Public Security Unit.	Cantonal policy-making: • strategies, cantonal laws and other regulations, • cantonal subsidy schemes, credit lines, projects. • Implementation of FBiH, Canton and, in few cases, state legislation. • Supervision of the application of relevant laws and regulations. • Administration of FBiH MoA subsidy schemes together with FBiH MoA and Municipalities. • Inspection supervision

Legal framework and competent institutions

At present BiH legislation in the agri-food sector is not yet fully in line with the EU acquis and WTO agreements. The current reforms in the sectors aim mostly at harmonizing legal frameworks with the EU acquis. Two sets of technical legislation exist in BiH: ex-YU legislation in combination with JUS mandatory standards and three framework laws in combination with BAS standards transposing European voluntary standards. Three framework national-level laws in BiH (largely in conformance with the EU acquis) are: the Veterinary Law (BiH Official Gazette # 34/02), the Food Law (BiH Official Gazette # 50/04) and the Law on Agriculture, Food and Rural Development (BiH Official Gazette # 50/08).

To add to the complexity, Entities have own laws that should be harmonized with existing state legislation, which is not always the case. In addition, the adoption of State level secondary legislation is slow with many by-laws still to be developed.

In period 2008/2009 there has been progress in this area and a number of technical regulations transposing related EU regulations/directives were adopted but enforcement remains weak. According to the EC Progress Report, October 2009. "the legislation on food control is not yet fully adopted and enforcement capacity remains weak and not in line with EU standards". Also, no progress was reported with regards the upgrading of agri-food establishments. It is stated that: "in BiH no technical regulations based on the product-specific acquis, including relevant conformity assessment procedures, have been adopted. Proper conformity assessment infrastructure (testing and calibration laboratories, certification and inspection bodies) is not yet in place".

BiH is still not fulfilling requirements related to SPS measures, which is a key requirement for EU market access. In case of export of animal products there are problems with fulfillment of requirements on animal health, animal identification and movement control as well as with the certifying body at the state level for registering and licensing the facilities. BiH does not have EU-registered processing facilities (except for fish) as yet, nor can it demonstrate that the required disease control mechanisms are in place.

The responsibility for the implementation of phytosanitary measure is in the jurisdiction of the FBiH MAWMF, RS MAFWM and the Agricultural Department of the District Brčko. Plant health border inspection is currently carried out by the Entity's ministries but is envisaged to be a future task of the Plant Health Administration. Importantly, EU Regulations pertaining to phytosanitary measures are becoming increasingly strict with respect to analysis of pesticide residues, phytosanitary certificates, implementation of a monitoring plan (as per IPPC) for quarantine pests/diseases for certain plants such as potatoes.

Since BiH does not have a Ministry of Agriculture at the state level, the Food Safety Agency is responsible for the transposition and adoption of food safety technical regulations.

Food safety Agency	•The Food Safety Agency (FSA) is founded under the direct responsibility of the Council of Ministers (CoM) of BiH. FSA is the central agency for risk analysis, handles traceability, recall, emergencies, information to consumers, proposes authorization of laboratories and defines criteria. FSA is the contact point for activities of the Codex Alimentarius Commission.
State Veterinary Office	•The State Veterinary Office is responsible for drafting veterinary legislation for the whole BiH, veterinary border inspection, international cooperation and coordination of activities of the entity's authorities. Each entity has its own chef of office and a different organization of the veterinary service.
Plant Health Administartion	•Plant Health Administration is responsible for drafting plant health legislation for the whole BiH, international cooperation and coordination of activities of the entity's authorities. BiH is a signatory of the International Plant Protection Convention (published in OG 8, 10/2003-International Agreements).

Institute for Metrology of Bosnia and Herzegovina

The CIPM Mutual Recognition Arrangement provides governments and other parties with a secure technical foundation for wider agreements related to international trade, commerce and regulatory affairs. It helps to eliminate technical barriers to trade and provide greater confidence in the measurement capabilities of individual countries. Legal metrology specifications are produced within the International Organization of Legal Metrology OIML and are adopted in all countries. Institute for Metrology of Bosnia and Herzegovina has become an associate member of European Cooperation in Legal Metrology (WELMEC). The planned strategy for the development of the metrology system has not yet been adopted. The metrology infrastructure has to be further

developed and the legislation harmonized with the European standards (EC Progress Report, October, 2009).

Institute of Standardization BAS

BAS is a full member of ISO, IEC, ETSI, associate member of CENELEC and a partner body of CEN. In accordance to with the overall country strategy toward EU integration and other international organizations, the main activity of BAS technical committees is the transposition of European Norms (EN) and ISO standards. BAS is responsible for the WTO TBT Enquiry Point, which is not functioning however, mostly because of lack of contact persons for TBT notification issues in the relevant ministries (EC Progress Report 2009). The process of adoption of EU standards is currently policy driven and not based on any analysis of sector demand for these standards. In accordance to EUTPP Trade related Needs Assessment Report, the sale of standards is quite low, especially with regards to SMEs although an upward trend is evident in recent times. At the same time, there is no economic justification for the conformity assessment bodies to apply the internationally accepted rules of procedure on offering their services, as there is no demand for them. The BiH companies wishing to export must use foreign conformity assessment bodies, which ass a substantial financial burden thus making it very difficult for them to be competitive on foreign markets. On the domestic market, in light of the lack of monitoring of the application of technical regulations, the protection of consumers is weak.

National Accreditation Body BATA

The area of accreditation in BiH is regulated by the Law on Accreditation (BiH Official Gazette No. 19/01) that is in accordance to international requirements. National accreditation body BATA was established in 2002 by the Law on Establishing the Institute for Accreditation of BiH (BiH Official Gazette of BiH no. 10/02). This legal framework enables BATA to join the European Accreditation and to enter into MRA.

Certification bodies must be accredited to attain international recognition. The trend in accreditation is to establish a worldwide network of national or regional groupings of accreditation bodies which will, through Multilateral Agreements (MLA), ensure that the competence of certification bodies and laboratories are assessed on the same principle regardless of where in the world they are located. Despite the legal basis for the international acceptance of the BiH accreditation system, obstacles such as absence of technical regulation on conformity assessment procedures, weak metrology system and lack the capacities and quality technical expertise remain before accreditation in line with international requirements is possible. Since 2009, BATA has an associate member status with ILAC, but the accreditation process has still not been initiated.

BiH needs to further establish the conditions for future international recognition of its tests, calibration results and certifications and prepare the country's Institute of Accreditation for signing MLA with the European Cooperation for Accreditation (EC progress Report 2009, EUTPP Trade related Needs Assessment Report 2007).

BiH Inspectorates

Three main inspectorates exist in Bosnia and Herzegovina: the Inspectorate of the Federation (includes 10 cantonal inspection bodies), the Inspectorate of Republika Srpska (includes 6 regional inspection bodies) and the Inspectorate of Brčko District. Only the veterinary service falls within the responsibility of the State Veterinary Office. There is no clear system of coordination, communication and chain of command between lower and higher levels of authorities, e.g., canton or municipality-level food inspections have no legal obligation to cooperate with the Entity Inspectorates and sometimes their responsibilities overlap (USDA Country Report 2009). Further

issue is that the inspection bodies are not accredited according to the ISO/IEC 17020 standard, which is an international requirement.

Current organizational structure and the legal framework for the inspection bodies is unclear resulting in overlap of jurisdiction and non-conformities with previously adopted State laws. This structure of inspectorates was formed in 2006 as inspection services were transferred from the entity agriculture, health and trade ministries into the entity inspectorates. This brought about additional confusion to the attempts of establishing an efficient national food safety and control systems, given that the entity solutions did not follow the legislative solutions adopted earlier at the State level4:

The 2003 Law on Plant Health Protection, which at the time of its adoption was entirely aligned with the EC requirements, introduces the phytosanitary inspection with clearly defined tasks, authorities and measures undertaken by the inspectors at the level of the entities and BD, whereas this matter within the Law on Inspectorates remained inseparably within the responsibility of agricultural inspection;

Under the 2002 Veterinary Law, production and trade of animal feed is within the responsibility of the veterinary inspection, whereas under the entity-level Laws on Inspectorates it falls within the responsibility of agricultural inspection.

BiH Laboratories

According to BiH legislation, the BiH Council of Ministers is authorized to enforce a procedure for assessment and authorization of laboratories, based on the recommendation provided by the BiH Food Safety Agency and prior recommendation of the Institute of Accreditation. Authorization is currently being given by Entity Ministries of health, agriculture or trade depending on the type of microbiological or chemical tests. All laboratories are required to follow Good Laboratory Practices (GLP) and, in case of authorized testing laboratories, are required to obtain accreditation from an independent institution.

There are quality requirements and prerequisites to be met by analytical laboratories for accreditation in accordance with ISO/IEC 17025. Proof of a laboratory's professionalism is provided, inter alia, by inter-laboratory proficiency tests in which several laboratories perform the same standardized tests and then compare their results. Such monitoring is essential if a laboratory is to be internationally recognized and "accredited". Approximately 30 laboratories in BiH have been accredited by BATA, however, since BATA itself is not accredited nor has it signed the MLA, the results obtained by the laboratories cannot be accepted outside of BiH.

Domestic and internationally-owned certification bodies in BiH

Companies in BiH that most frequently undertake certification in accordance with international standards are foreign-based certification bodies such as TÜV Thüringen, TÜV Adria, Quality Austria, Boscert, Soil Association UK, IMO, Aranea Certifiering AB, ICEA and others. The only domestic, internationally-accredited certification body in the agri-food sector is Organska Kontrola (OK) which provides certification in organic production.

OK is accredited by IOAS according to IFOAM accreditation criteria. OK also hold accreditation against ISO/IEC Guide 65 (EN45011) that is obligatory requirement in accordance to EC Regulation. As EU passed a "new" Reg. on organic agriculture (EC Reg. 834/2007, that comes into force 01/01/2009) OK has been assessed in 2009 as EU equivalent body by IOAS and a request to EC for a recognition of OK as a Control Body from third countries for the purpose of

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4 FAO program „ Strengthening food safety in South East European transition countries" 2007 ; Sida Project 2008: "Quality and Regulatory Infrastructure Development for Food safety and Quality in South East Europe", Marijo Perc;

equivalence has been submitted to EU. It is expected that first list of approved bodies from third countries will be published in 2010. In the absence of a National Law on organic agriculture, OK has developed private standards for organic certification and a conformity assessment has been done for both OK standards as well as for certification program of OK.

Whilst it is important to have certification bodies, equally important is the availability of consultants that can provide assistance to companies to meet certification requirements. The number of adequately-trained consultants that can provide such assistance is still quite small. The greatest number of available consultants is in relation to ISO standards and HACCP and most of these consultants have been trained by international donor projects.

Adoption of private standards amongst Producer Organizations in BiH

Some of export-oriented producers and processors realize the benefits of introducing and implementing ISO standards, HACCP, GlobalGAP as well as organic certification as it leads to improved competitiveness and increased opportunities on the international market. Organic certification provides access to high-paying markets as premiums are paid to organically certified products.

Most POs that are exporting have completed the certification process with various international certification bodies, as certification is required to demonstrate compliance with the standards due to the lack of proper conformity assessment infrastructure in BiH. However, most of the POs that are selling their produce domestically, have adopted only the standards required by local laws, and they are not aware of many advantages that can be gained with implementation of standards and certification. In general, there is a lack of awareness about the importance of certification and safer and more superior quality products.

POs that are working towards meeting other standards required by their preferred market are encountering problems. According to the interviews conducted by FARMA, the most frequent constraints cited by companies trying to meet international standards and export products to the EU are:

- Lack of accredited institutions (whether this be laboratories or certification bodies) in BiH that can issue internationally recognized (valid) certificates. This increases the cost of certification since the POs must obtain the service directly from the EU certifier or BiH organization that works in cooperation with EU certifiers;

- In some instances there is a difficulty in "compiling" export certificate because for one shipment of goods it may be necessary to provide results of laboratory tests that had to have been conducted in several laboratories (e.g. radiological tests, heavy metals, pesticide residues etc.) or issued by different inspectorates;

- The domestic market is under-regulated allowing conventional products to be sold on the market with organic labels;

- There is a lack of technical assistance providers (as consultancy services for example) for certain standards and certification processes;

- The costs of implementation of standards (training, consultancy services) as well as the cost of certification itself, can be very high especially for SMEs.

Conclusion

Meeting stringent EU food safety standards is a key requirement for EU market access. Comprehensive management systems such as international agreements, standards, protocols and guidelines are indicative of the serious efforts under way to ensure food quality and safety. In BiH, there is a lack of awareness and application of appropriate procedures to meet international food safety standards and product traceability requirements for the domestic and export market. In addition, implementation of QMS and standards is hampered by lack of institutional support including accredited laboratories.

It is clear that BiH must adopt the agriculture/food standards on its path towards the European Union. If BiH companies and agriculture producers wish to trade on the global market, they also need to build capabilities to increase their supply capacity, quality, competitiveness and conformity with importer mandated standards. While the development of BiH POs offers potential for development and economic growth, problems with meeting requirements of the standards, confusing system of mandatory and voluntary standards, national, regional or international level of standards are considered a significant constraint to achieving this growth and a key limiting constraint to EU market access.

As such, BiH needs to:

- Improve the quality and regulatory infrastructure

- Assist producers and processors meet the required standards

Improving quality and regulatory infrastructure

Improving quality and regulatory infrastructure in BiH, as required by international standards and the EU *acquis*, is a complex task. This process is however underway and is being supported by EC-funded projects as well as other donors, including Sida.

The role of FARMA in this process should be to leverage its activities with other donors to provide targeted assistance to institutions that are playing a key role in overcoming the barriers to export produce to the EU. Specific examples may include:

- Assistance to BiH Plant Health Administration in the establishment of a monitoring system for quarantine pests for potatoes. Without an EU-recognised monitoring system, BiH producers cannot export fresh potatoes to the EU.

- Assistance to State Veterinary Office in the successful establishment of a National Monitoring Plan – National Residue Control Program in order to resolve SPS issues pertaining to the export of honey to the EU;

- Assistance to targeted laboratories to meet accreditation requirements in close coordination with other donor projects.

- Strengthening of the accreditation system by training external auditors in ISO 17025.

- Assistance to local organic certification body (OK) to provide a wider range of services to ensure its long-term sustainability and continual provision of quality, cost-effective certification service.

- A comprehensive set of activities to align the development of entity and state legislation on organic production with the EU *acquis*.

Assisting producers and processors to meet required standards

Producer Organizations need to be assisted to meet relevant standards and obtain certification to have sounder business practices and therefore achieve anticipated food safety and environmental benefits as well as access EU markets.

The role of FARMA in this process should be to leverage its activities with other donors to provide targeted assistance to POs to implement standards and obtain necessary certifications to access desired international markets. The overall aim of the above activities is to ensure that POs have the capacity to produce food that meets international standards.

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Useful websites

http://europa.eu.int/eur-lex/lex/RECH_menu.do?ihmlang=en

http://export-help.cec.eu.int/

http://europa.eu.int/eur-lex/lex/en/repert/index.htm

http://mkaccdb.eu.int/

http://europa.eu.int/comm/dgs/health_consumer/index_en.htm

http://europa.eu.int/comm/food/plant/protection/pesticides/index_en.htm

www.codexalimentarius.net.

www.ipfsaph.org/En/default.jsp

www.wto.org

http://www.agrifoodstandards.net

http://agritrade.cta.int/en/content/view/full/

http://www.foodnavigator.com/

http://www.foodqualitynews.com/

http://www.rssl.com/OurServices/FoodENews/

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